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REMARKS

This Amendment and Reply seeks to place this application in condition for allowance. Certain claims have been amended to more clearly describe the invention, to improve grammar, to correct inadvertent typographical errors, to improve antecedent bases, and to address the Examiner's concerns regarding clarity. No new matter has been added.

In addition, Applicants have added seven (7) new dependent claims to more fully protect the inventions. No new matter has been added.

All of the objections and rejections raised in the Office Action of September 1, 2006 (hereinafter the "Office Action") have been addressed in detail below.

Claim Objections

Briefly, Applicants have amended the claims to address the concerns raised by the Examiner in claims 8, 14, 15, 38 and 40. The undersigned appreciates the Examiner's thorough review.

In addition, Applicants have amended other claims to address clarity and antecedent bases. (See, for example, claims 24, 26, 28, 29, 47 and 48). No new matter has been added.

Claim Rejections – 35 USC §112

On pages 3 and 4 of the Office Action, the claims were rejected as being based on a non-enabling disclosure and as being indefinite. Although Applicants do not entirely understand the rejections, Applicants have amended the claims in an effort to eliminate any confusion as to what is claimed.

Claim Rejections – 35 USC §112, First Paragraph

Applicants respectfully disagree that critical or essential aspects of the glucose sensor have been omitted from the claims. In an effort to eliminate any confusion and more clearly define what the Applicants regard as their invention, the claims have been amended to recite a "glucose sensor". This is consistent with the terminology in the specification, wherein it is often more broadly/generally described as a "sensor". (See, for example, (1) page 8, line 13 to page 10, line 3, (2) page 10, line 4 to page 11, line 5, (3) page 19, line 1 to page 20, line 18, and (4) page 22, lines 6-16). Thus, in amended claims 1-15 and 30-67, Applicants seek to protect a glucose sensor.

There is no question that the sensor is a portion of the larger sensing system. (See, for example, page 11, line 6 to page 18, line 22). However, in claims 1-15 and 30-67, Applicants seek to protect the inventive glucose sensor -- separate from the instrumentation.[1] For example, in claim 1, Applicants describe a glucose sensor for implantation within subcutaneous tissue of an animal body, the glucose sensor of claim 1 comprises:

- a first chamber containing (i) first magnetic particles and (ii) a first hydrocolloid solution having a viscosity which is dependent on and/or a function of the concentration of glucose in the first chamber, wherein the first magnetic particles are dispersed in the first hydrocolloid solution and wherein, when the first chamber is implanted in subcutaneous tissue of an animal body, glucose in the animal body may enter and exit the first chamber; and
- a reference chamber containing a reference solution and second magnetic particles dispersed in the reference solution, wherein, when the reference

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[1] Notably, in claims 16-29, Applicants seek to protect a glucose system including a sensor and instrumentation.

> chamber is implanted in subcutaneous tissue of the animal body, glucose in the animal body does not enter the reference chamber.

The instrumentation is not essential to the glucose sensor. Indeed, based on the specification, the instrumentation is not an element of the sensor. The instrumentation 24 (which, in certain embodiments set forth in the specification, includes optical fibers, light sources, magnet and instrumentation (for example, a spectrum analyzer) -- see Figure 2) elements are directed to the sensing system which includes instrumentation to, for example, determine data which is representative of a change in viscosity of the hydrocolloid solution in the first chamber. (See, for example, claims 16-29). Applicants have described and illustrated many different configurations, circuits and techniques in regards to instrumentation 24. (See, for example, Figure 2 and page 11, line 6 to page 18, line 22). This notwithstanding, the specification clearly describes the inventive sensor 12 being separate from and not a part of instrumentation 24. Indeed, the specification, as filed, describes and illustrates many embodiments of the sensor. For example, sensor 12 includes

> glucose chamber 14 and reference chamber 16. The sensor 12, in one embodiment, is implanted into or beneath the skin barrier of an animal body using a small needle-type instrument. In this regard, sensor 12 may be disposed within the subcutaneous tissue when the small needle-type housing is introduced through the skin. Thereafter, sensor 12 may be affixed in place within subcutaneous tissue after the small needle-type housing is withdrawn.
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> In one embodiment, glucose and reference chambers 14 and 16, respectively, include magnetic (e.g., paramagnetic, superparamagnetic, and/or ferromagnetic) particles 18a and 18b, respectively, that are dispersed in a Concanavalin A ("ConA") - dextran hydrocolloid (for example, 5% dextran (Mw 2000 kDa) and 1% ConA (volume of 0.5 μl)). In one

> embodiment the magnetic particles 18a and 18b are may be a particle or particles which may be made or caused to move under the influence of a magnetic field or magnetomotive force, for example, amine-terminated particles having mean diameter of about 1 μm (Bangs Laboratories, Inc., Part No. MC05N). As such, the magnetic particles may include rare earth elements like neodymium and samarium and compounds like neodymium-iron-boron and samarium-cobalt, and ferromagnetic materials including iron, permalloy, superpermalloy, cobalt, nickel, steel, and alnico. Indeed, any and all particles that may be caused to move under the influence of a magnetic field or magnetomotive force, whether now known or later developed, are intended to be within the scope of the present invention.
>
> When implanted, the glucose in the tissue surrounding the sensor 12 may enter glucose chamber 14 and may interact with the medium in the chamber, including the concanavalin A ("ConA") - dextran hydrocolloid to effect, alter, modify and/or change the viscosity of the medium within chamber 14. The resultant viscosity, in turn, may determine, effect, alter, modify or change the rate at which the magnetic particles 18a move, travel or migrate through the medium of glucose chamber 14 ....
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> In one embodiment, glucose chamber 14 includes a semipermeable membrane. In this regard, glucose chamber 14 may be comprised of a material which retains the sensing medium and, in addition, allows concentration driven transport of glucose into and out of the chamber (for example, a hollow micro dialysis fiber). In one embodiment, glucose chamber 14 may be comprised of regenerated cellulose, polyurethane, polysulfone, and/or other material that is capable of unrestricted (or substantially unrestricted) glucose in and efflux.
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> (page 8, line 13 to page 10, line 3).

Notably, there are many other embodiments of the sensor described in the specification. (See, for example, (1) page 10, line 4 to page 10, line 22, (2) page 19, line 1 to page 20, line 18, and (3) page 22, lines 6-16).

In sum, it is believed that the amendments to the claims have addressed the Examiner's concerns. The claims make clear that Applicants seek to protect the "glucose sensor". The specification amply describes and enables the claimed sensor. The specification makes clear that instrumentation 24 (which includes, in one embodiment, optical fibers, light sources, magnet and instrumentation -- see Figure 2) is not an element of sensor 12. Moreover, instrumentation 24 is not a critical or an essential element with respect to the sensor -- which is the focus of claims 1-15 and 30-67. Applicants respectfully request withdrawal of the rejection.

Claim Rejections – 35 USC §112, Second Paragraph

The claims were rejected as being indefinite for failing to claim essential matter. Applicants respectfully disagree. As discussed in detail above, the claims make clear that Applicants seek to protect the "glucose sensor". The instrumentation is not a critical or an essential element with respect to the glucose sensor -- which is the focus of claims 1-15 and 30-67. Indeed, the instrumentation is not an element of the sensor.

The claims describe elements of the glucose sensor. The claims do not simply list unrelated items. For example, claim 30 recites, among other things, a glucose sensor for measuring the concentration of glucose in a fluid medium, comprising:

- a first chamber containing (i) first magnetic particles and (ii) a hydrocolloid solution having a viscosity which is dependent on and/or a function of the concentration of glucose in the first chamber, wherein the first magnetic particles are dispersed in the hydrocolloid solution and wherein, when the first chamber is fluidic contact with the fluid medium, glucose from the fluid medium may enter and exit the first chamber; and

- a reference chamber containing a reference solution and second magnetic particles dispersed in the reference solution, and wherein, when the reference chamber is in fluidic contact with the fluid medium, glucose from the fluid medium does not enter the reference chamber.

The elements set forth in the last paragraph on page 4 of the Office Action are not essential to the claimed glucose sensor. Indeed, based on the specification, such elements are not even an element of the sensor. (See, for example, Figure 2). Rather, the elements are directed to the sensing system which includes instrumentation to, for example, determine data which is representative of a change in viscosity of the hydrocolloid solution in the first chamber. (See, for example, claims 16-29).

Notably, Applicants have described and illustrated many different configurations, circuits and techniques in regards to instrumentation 24. (See, for example, page 11, line 6 to page 18, line 22). This notwithstanding, the specification clearly describes the inventive sensor being separate from the instrumentation.

It is believed that the amendments to the claims have addressed the Examiner's concerns. The claims make clear that Applicants seek to protect the "glucose sensor". The instrumentation is not a critical or an essential element of the claimed sensor. The specification clearly describes the instrumentation as not being an element of the sensor. Applicants respectfully request that the rejection be withdrawn.

Allowable Subject Matter (Page 5 of the Office Action)

Bucalo (U.S. Patent 4,005,699) and Lee (U.S. Patent 4,419,383) have been identified as "the most relevant prior art." (Office Action, page 5). In short, neither Bucalo nor Lee teach or suggest the claimed inventions. Indeed, neither Bucalo nor Lee teach or suggest a glucose sensor.[2]

Notably, although the Examiner has correctly noted that the apparatuses of Bucalo and Lee are incapable of sensing glucose concentration, Applicants do not agree with the application and characterization of Bucalo and Lee to the claims. For example, neither Bucalo nor Lee teach or suggest:

- a glucose sensor and/or glucose sensing system having a first chamber containing (i) first magnetic particles and (ii) a first hydrocolloid solution having a viscosity which is dependent on and/or a function of the concentration of glucose in the first chamber, wherein the first magnetic particles are dispersed in the first hydrocolloid solution and wherein, when the first chamber is implanted in subcutaneous tissue of an animal body, glucose in the animal body may enter and exit the first chamber; (see, for example, independent claims 1, 16 and 30);
- a glucose sensor having a reference chamber containing a solution, and magnetic particles dispersed in that solution, wherein, when the reference chamber is implanted in subcutaneous tissue of the animal body, glucose in the animal body does not enter the reference chamber. (See, for example, independent claims 1);
- a glucose sensor which is implanted in subcutaneous tissue of an animal body and instrumentation to determine data which is representative of a change in viscosity of a hydrocolloid solution in a first chamber of the glucose sensor (See, for example, independent claims 16); or
- a glucose sensor having a reference chamber containing a solution, and (magnetic particles dispersed in that solution, wherein, when the reference

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[2] It is unclear as to what is meant by "no prior art has been applied to claims 2, 3, 5-15, 17-29 and 31-59." Why? (Compare MPEP 2143.03). Indeed, it appears that no art rejections have been made.

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chamber is in fluidic contact with a fluid medium, glucose from the fluid medium does not enter the reference chamber. (See, for example, independent claims 30);

- a glucose sensor including a first solution disposed in a first chamber, wherein the first solution includes a viscosity which is dependent on and/or a function of the concentration of glucose in the first chamber, a plurality of magnetic particles which are dispersed in the first solution, wherein when the first chamber is in fluidic contact with the fluid, glucose in the fluid may enter and exit the first chamber. (See, for example, claim 49).

In sum, for at least the reasons set forth above, the pending claims are neither anticipated by nor obvious to one skilled in the art in view of Bucalo and/or Lee. Notably, the reasons set forth above are *not* the only reasons the inventions of the independent claims (or dependent claims) are patentable over Bucalo and Lee, either alone or in combination. For the sake of brevity, the remarks above highlight some of the patentable aspects of the independent claims. No inference or conclusion should be drawn that Applicants' response to this rejection is exhaustive.

CONCLUSION

Applicants respectfully request entry of the foregoing amendments and reconsideration of the instant application. Applicants submit that all of the pending claims present patentable subject matter and allowance of the claims is respectfully requested.

It is noted that should a telephone interview expedite the prosecution of this application in any way, the Examiner is invited to contact the undersigned.

Respectfully submitted,

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